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(54) Title: <b>UNIQUE ELECTRODE CONFIGURATIONS FOR CARDIOVASCULAR ELECTRODE CATHETER WITH BUILT-IN DEFLECTION METHOD AND CENTRAL PULLER WIRE</b>			
(57) Abstract			
<p>An electrophysiological mapping device includes an outer catheter (8), an inner catheter (6) slidably within the outer catheter, and an electronic activation and recording device (4) for electrically activating electrodes (11) on the inner catheter and/or recording electric signals received by the electrodes. The distal end of the inner catheter comprises a plurality of arms (9) that carry electrodes. The arms bow outwardly upon extension of the inner catheter from the outer catheter to form a three-dimensional shape. Each arm has a spine (25) of a super-elastic material. Each spine is semicircular in section, and is disposed within a portion of a flexible sheath (18), the electrode lead wires being disposed in the rest of the sheath. The electrodes are formed from the ends of the insulated electrode lead wires (20) which pass through the sheath, are wrapped around the sheath and then stripped of their insulation.</p>			

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**UNIQUE ELECTRODE CONFIGURATIONS FOR  
CARDIOVASCULAR ELECTRODE CATHETER WITH  
BUILT-IN DEFLECTION METHOD AND CENTRAL PULLER WIRE**

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**Field of the Invention**

The present invention relates to cardiovascular catheters and, in particular, to such catheters having a retractable basket-shaped electrode array formed by a plurality of arms, each arm supporting a plurality of spaced-apart electrodes.

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**Background of the Invention**

Electrophysiology is a specialty within the field of cardiology for diagnosis and treatment of electrical abnormalities of the heart. Diagnosis is performed using electrode-bearing catheters placed within the heart chambers. Electrodes 15 are positioned along a catheter shaft in a primarily two-dimensional array, although electrode elements spaced laterally around the catheter shaft give the array a very limited third dimension. Understandably, this third dimension is limited because of the small catheter shaft diameter required for such catheters as they are introduced into the heart via the veins and arteries of the body.

20 Electrical abnormalities are typically diagnosed by detecting the course of electrical activation paths along the endocardial surfaces of the heart chambers over time. To do this, the cardiologist may place several catheters within one or more chambers of the heart to get a better "picture" of this electrical activity. Sometimes this electrical activity is cyclical, i.e., repeats fairly well from 25 heartbeat to heartbeat. In such cases, one catheter may serve to perform the diagnosis by moving the electrodes to various regions and then point-by-point comparing activation times with a reference. This reference may be the external EKG or another electrode catheter maintained in a stable position within a heart chamber.

30 However, certain types of electrical activity within a heart chamber are not cyclical. Examples include arterial flutter or arterial fibrillation, and ventricular tachycardia originating in scars in the wall of the ventricle that have resulted from infarcts. Such electrical activity is random from beat to beat. To analyze or "map" this type of electrical activity, the "picture" must be obtained during 35 one beat. In other words, all the points of the map or picture must be obtained simultaneously within one-tenth of a second.

1           One solution to improve mapping is disclosed in U.S. Patent  
Nos. 4,522,212 to Gelinas et al. and 4,699,147 to Chilson et al. which are  
incorporated herein by reference. In these patents, a catheter has, at its distal  
end, multiple lead-carrying arms which extend in a three-dimensional array, each  
5           arm having an inner central rib and electrodes spaced along its length. In Chilson  
et al., the arms are fixed at their distal end, but free to move within an outer  
catheter tube at their proximal end. The lead-carrying arms may be retracted into  
and extended from the outer catheter tube. The distal end of the catheter is  
directed to the designated areas of the heart and withdrawn, with the  
10          lead-carrying arms retracted within the outer catheter tube. Once at the  
designated areas, the arms are extended from the outer catheter tube to form a  
three-dimensional shape, referred to as an "elliptical envelope."

15          The catheter described in Chilson et al. is able to hold a large number of  
electrodes in different relative positions within a heart chamber. By this means,  
the cardiologist can obtain a map of electrical activity in one heartbeat by  
recording electrical signals from all the electrodes simultaneously. This is done  
by analyzing the spatial and temporal relationship of the electrical signals  
received at the electrodes.

20          By rotating the catheter and/or moving it longitudinally and recording  
electrical signals, a series of maps or pictures can be produced. A series of such  
pictures provides a "moving" picture of successive heartbeats, which may be  
able to better define the ectopic sites of activation or other activation pathways  
that contribute to the malfunction. This type of information may then allow the  
cardiologist to intervene with another catheter to destroy that causative tissue.  
25          Such destruction of heart tissue is referred to as "ablation," which is a rapidly  
growing field within electrophysiology and obviates the need for maximally  
invasive open heart surgery.

30          In Chilson et al. the arms are easily moved relative to each other and  
hence, the shape of the elliptical envelope varies from time to time and may vary  
even when positioned in one place due to the pumping heart chamber or the  
effect of rotation. Accordingly, the spatial relationship of the electrodes is  
subject to variation of unknown amounts. This, in turn, imparts a high degree  
of uncertainty or error in any map of electrical activity produced with the use of  
this catheter.

35          To obtain additional improvements in mapping, Chilson et al. and U.S.  
Patent Nos. 5,156,151 and 5,324,284 both to Imran, which are incorporated  
herein by reference, utilize an internal puller wire to expand and stabilize the

1 three-dimensional shape. The puller wires of Chilson et al. and the Imran references extend through catheter lumens which are not sealed against the flow of blood at either the proximal or distal ends of the catheters, and the puller wires of Chilson et al. and Imran are not coated. Thus, the puller wire is in direct  
5 contact with the lead wires and/or the catheter wall. Because the Chilson et al. and Imran puller wire is in direct contact with the lead wires and/or the catheter wall, which are fixed relative to the puller wire, the puller wire can become impinged between the lead wires when the catheter is bent preventing translation of the puller wire through the lumen. Further, when the puller wire is in direct  
10 contact with the lead wires, the puller wire can wear off the insulation of the lead wires or even sever the lead wires thereby destroying the catheter. Because the distal end of the catheter is not sealed against the flow of blood or air, blood can infiltrate the lumens of the catheter thereby preventing effective cleaning and sterilization of the catheter for reuse, and air can be introduced  
15 through the catheter into a blood vessel or the heart creating a potentially fatal air embolism.

#### Summary of the Invention

20 The present invention provides an electrophysiological mapping catheter comprising an outer catheter and an inner catheter. The inner catheter comprises a tubular shaft extending longitudinally through the outer catheter tube. At the distal end of the shaft, there is a plurality of flexible arms, each arm carrying a plurality of spaced-apart electrodes. The flexible arms of the basket are fixed at their proximal ends to a proximal fitting and fixed at their distal ends to a distal fitting. The shaft is movable longitudinally within the outer catheter and the arms and electrodes can be retracted into and extended from the outer catheter tube. When the arms are extended out of the catheter tube, the arms flex  
25 outwardly to form a "basket," the electrodes forming a three-dimensional array.

30 Each arm comprises a reinforcing spine surrounded by a tubular flexible sheath having a generally circular cross-section. Each reinforcing spine preferably has a semicircular cross-section with the flat surface of the spine facing inwardly, i.e. toward the axis of the catheter. The spines preferably lie in the outwardly facing portion of the tubular sheath with the remainder of the tubular sheath filled by insulated electrode lead wires.

35 The electrodes are preferably formed on the arms by passing insulated lead wires through the wall of the tubular sheath, wrapping the wires around the tubular sheath and gluing it thereto. The insulation is then stripped off the outer

1       surfaces of the lead wires which are wrapped around the sheath. The electrode lead wires extend from the arms through the proximal fitting and through the lumen of the inner catheter shaft to a stimulation and/or recording device.

5       The proximal and distal fittings include polygonal rod segments whose flat sides correspond in number to the number of spines and engage the flat surfaces of the spines. A clamping ring is positioned around the spines to hold them in proper orientation on the polygonal rod segment. In a preferred embodiment, the spines are formed out of a superelastic material, particularly a nickel-titanium alloy, with "shape memory." Such material returns to its bowed shape upon extension of the arms out of the outer catheter.

10      Also provided is a tubular catheter shaft with a plurality of arms forming a three-dimensional shape at the distal end of the catheter shaft. Each arm has at least one electrode with an electrode lead wire connected thereto. A puller wire extends through a lumen of the catheter and is attached to the distal end 15 of the basket shape such that the basket shape can be expanded by a proximally directed force applied to the puller wire. The lumen of the catheter shaft is closed at the distal end. In another embodiment of the invention, the puller wire is coated.

15      Further provided is an electrode configuration having a plurality of continuous electrode arms forming a three-dimensional shape. Preferably, portions of the electrode arms are coated.

20      Still further provided is a method of coating the electrode arms in which a coating material is dissolved in a solvent to form a solution. The solution is applied to the electrode arm and cured thereon.

25

#### Brief Description of the Drawings

FIG. 1 is an enlarged view of the distal end of an inner catheter and an outer catheter with the inner catheter extended from the outer catheter, thus forming a basket of electrodes at the distal end of the inner catheter;

30      FIG. 2 is an enlarged view of an electrode pair from the circled portion labeled "2" in FIG. 1;

FIG. 3 is a longitudinal cross-sectional view of the distal end of the inner catheter shaft;

35      FIG. 4 is an enlarged transverse sectional view taken along line 4-4 of FIG. 1 and showing one arm of the basket of FIG. 1;

FIG. 5 is a transverse sectional view of a proximal fitting which has been taken along line 5-5 of FIG. 1;

1 FIG. 6 is a transverse sectional view of a distal fitting of the basket of  
FIG. 1 taken along line 6-6 of FIG. 1;

2 FIG. 7 is a schematic view of the ten asymmetric positions of rotation;

3 FIG. 8 is a partial perspective and partial schematic view of an  
5 electrophysiological mapping system according to the invention, including an  
inner catheter, an outer catheter, and an activation and recording device,  
showing the inner catheter retracted within the outer catheter;

6 FIG. 9 is an elevational view of a catheter having a basket of electrodes  
in a relaxed position with a coated puller wire and a deflectable control handle  
10 for activation of the puller wire;

11 FIG. 10 is an elevational view of the basket of FIG. 9 in an expanded  
position;

12 FIG. 11a is a cross-sectional view taken along line 11-11 of FIG. 9  
15 illustrating the proximal end of the basket;

13 FIG. 11b is a cross-sectional view taken along line 11-11 of FIG. 9  
illustrating the proximal end of the basket and an alternate embodiment of the  
coating on the puller wire;

14 FIG. 12 is a cross-sectional view taken along line 12-12 of FIG. 9  
18 illustrating the distal end of the basket;

15 FIG. 13 is an elevational view of an alternate electrode configuration;

16 FIG. 14 is an elevational view of another alternate electrode configuration;

17 FIG. 15 is an elevational view of still another alternate electrode  
20 configuration;

18 FIG. 16 is an elevational view of a further alternate electrode  
25 configuration;

19 FIG. 17 is a cross-sectional view taken along line 17-17 of the electrode  
in FIG. 16;

20 FIG. 18a is an elevational view of the electrode configuration of FIG. 16  
having the proximal ends of the electrodes completely coated;

21 FIG. 18b is a cross-sectional view taken along line 18b-18b of the  
25 electrode in FIG. 18a;

22 FIG. 19a is an elevational view of the electrode configuration of FIG. 16  
having the distal ends of the electrodes completely coated;

23 FIG. 19b is a cross-sectional view taken along line 19b-19b of the  
30 electrode in FIG. 19a; and

24 FIG. 19c is a cross-sectional view taken along line 19c-19c of the  
35 catheter in FIG. 19a.

1        Detailed Description of the Preferred Embodiment

With reference to FIGS. 1, 2, and 8 a preferred electrophysiological mapping system is shown. The system includes an electronic stimulation and/or recording device, an inner catheter 6, and an outer catheter tube 8. Outer catheter tube 8 carries inner catheter 6 to a mapping site, e.g., within a heart chamber, and also serves to withdraw the inner catheter 6 from the mapping site. Inner catheter 6 is slidable longitudinally within outer catheter tube 8. FIG. 8 shows the mapping system, including electronic stimulation and/or recording device 4, and inner catheter 6 retracted within outer catheter tube 8.

10      Inner catheter 6 comprises an elongated, tubular catheter shaft 7 and five electrode carrying arms 9 at the distal end of the catheter shaft 7. Inner catheter 6 can be moved relative to outer catheter tube 8 between an extended position as shown in FIG. 1 wherein arms 9 extend completely out of the distal end of outer catheter tube 8 and a retracted position generally as shown in FIG. 8 wherein the arms 9 are retracted within the outer catheter tube 8. In the extended position, the arms 9 bow outwardly to define a "basket" structure.

15      Each arm 9 has its own spaced set of ten electrodes 11, shown herein as five bipolar electrode pairs. In the embodiment shown, the five electrode pairs are generally evenly spaced. It is understood, however, that the number and spacing of the electrodes may vary as desired. Further, single electrodes may be used rather than bipolar electrode pairs.

20      The arms 9 are fixed at their proximal ends to a proximal fitting, generally designated 12, and also fixed at their distal ends to a distal fitting, general designated 14. Proximal fitting 12 is, in turn, fixed to the distal end of the catheter shaft 7. The catheter shaft 7 comprises a central lumen 13 which extends from its proximal end to its distal end. The shaft 7 preferably comprises a tubular wall 10 of high-strength braided stainless steel or other high-strength wire or fiber, sandwiched between inner and outer layers of firm, yet flexible, polyurethane, for example, as disclosed in U.S. Patent Application No. 07/645,230, filed January 24, 1991, incorporated by reference herein. This high-torque shaft structure allows a physician to control the orientation of the electrode basket within the heart chamber by rotating the catheter shaft 7 where it enters the patient's body, which is usually at the groin or neck. The shaft 7 preferably further comprises a nylon stiffening sleeve 15 lining the interior of the tubular wall 10.

25      FIG. 4 is a sectional view of an arm 9. The arm 9 has an outer tube/sheath 18 of a flexible insulating material, e.g., a plastic such as flexible

1 polyurethane tubing. Inside the plastic tubing are the plurality of electrode lead  
wires 20, each wire having an insulation coating 21 and a central conductive  
wire core 23. The wires 20 extend from the electrodes 11 through the plastic  
tubing 18 of the arms 9, through the proximal fitting 12 and lumen 13 of the  
5 shaft 7 to the stimulation and/or recording device 4. In this embodiment, there  
are fifty lead wires 20 which correspond to the ten electrodes 11 carried on each  
of the five arms 9. The number of electrodes and, hence, electrode lead wires  
may be varied as needed.

10 Referring to FIG. 3, the lead wires 20 are separated into five bundles 22,  
each bundle 22 containing the ten lead wires 20 which correspond to the ten  
electrodes 11 carried by each particular arm 9. At their proximal ends, the  
separate wire bundles 22 terminate in separate plug connectors 24, which are  
plugged into the activation and recording device 4 (FIG. 8). The total number of  
15 lead wires 20 in each bundle 22 is equal to the number electrodes 11 on each  
corresponding arm. Therefore, if there are 5 electrodes on each arm, there will  
be 5 leads in the corresponding bundle. If there are 5 electrode pairs, there will  
be 10 electrode leads in the bundle. Each bundle 22 of leads is contained in an  
insulated flexible tube, which in turn enters the plug connector.

20 With reference to FIG. 2, each electrode 11 is formed by passing a lead  
wire 20 through the outer sheath 18 of the arm 9. The wire 20 is wrapped  
tightly around the sheath 18 and glued and then the insulation coating from the  
outwardly facing surfaces of the lead wires, i.e. the surfaces which will contact  
the heart wall, is stripped to expose the metal of the lead wire.

25 It is preferable that the electrode lead wires 20 be of a metal which is  
inert in blood. MONEL 400, which is a trademark of Huntington Alloy Products  
Division of International Nickel Co., Inc., Huntington, West Virginia, is presently  
preferred. MONEL refers to a group of corrosion-resistant alloys of  
predominantly nickel and copper and very small percentages of carbon,  
manganese, iron, sulfur, and silicon. Some such alloys also contain a small  
30 percentage of aluminum, titanium, and cobalt. MONEL 400 has the additional  
benefit that it is not as easily visible under fluoroscopic x-ray as platinum.  
Therefore, the electrodes can be small and all of equal size and uniformly  
arranged.

35 With materials which are more radiopaque, even spacing of the electrode  
is not desirable because it is difficult to distinguish which arm is at which  
location. For example, in U.S. Patent No. 4,699,147 to Chilson et al., the  
electrodes on one arm are spaced unevenly with respect to the electrodes on

1       each other arm. If the electrodes were spaced evenly in the device of Chilson  
et al., it would be difficult to identify which arm is which under x-ray. In the  
preferred embodiment of the present invention, the electrode pairs on each arm  
are able to be spaced evenly with respect to each other and are located on  
5       corresponding positions to the electrodes on each other arm, although uneven  
spacing on each arm and staggered spacing with respect to the electrodes on  
other arms is acceptable.

10      The even spacing of electrodes would normally result in difficulty  
determining which arm is at which location. However, in accordance with one  
aspect of the invention, markers 38, at different locations along each arm, such  
as in a staggered or spiral pattern, are positioned on the arms, respectively.  
These markers preferably are of a material which is easily identifiable under  
fluoroscopic x-ray, such as platinum, and are in the shape of a band or ring fixed  
around each arm.

15      The arms 9 are supported by a flexible rib or spine 25 having a  
semicircular cross-section which runs through the outer tube 18 as shown in  
FIG. 4. The spine 25 is preferably formed out of a superelastic material, such as  
a nickel-titanium alloy having about 54 to 57% nickel, preferably 55%, and the  
remainder is titanium, preferably 45%. Such materials exhibit "shape memory."  
20      That is, it can be deformed by an external stress, e.g. bent, and, when that  
stress is removed, it will return to its original shape. A presently preferred  
material is sold under the trademark NITINOL by U.S. NITINOL of Saratoga,  
California. Such a superelastic spine 25 allows the arms 9 of the basket to be  
retracted into and extended from the outer catheter tube 8 and otherwise  
25      subjected to bending, such as from the beating heart chamber, yet still return to  
its proper shape, even if extremely deformed.

30      The spine 25 preferably has an insulation coating 33, e.g., of  
polyurethane paint, to help hold it in place and shield it from the lead wires. The  
lead wires 20 and spine 25 are positioned in sheath 18 such that the spine 25  
occupies the outwardly facing portion of the sheath 18, while the lead wires 20  
35      occupy the inwardly facing portion of the sheath 18. The terms "outwardly" and  
"inwardly" are relative to an axis or centerline of the basket. Spines 25 having  
a semicircular cross-section are preferred over spines having circular  
cross-sections of the same cross-sectional area because they provide greater  
lateral stability, yet have sufficient flexibility for opening into the "basket" shape  
when the inner catheter 6 is extended out of and collapsed into outer catheter  
tube 8.

1        The positioning of the electrode lead wires 20 in the inward portion of the tube 18 places the wires 20 away from the heart wall. This enables the wire portion used for the electrodes 11 to pass through the sheath 18 at a location remote from the heart wall and thereby provide a smoother electrode surface.

5        The hole in the sheath 18 through which the lead wire 20 extends and lead wire terminus is preferably covered and secured with an adhesive, e.g., polyurethane, in a position where it will not be in contact with the heart chamber wall.

10      The metal portion of each spine 25 extends beyond the plastic tubing 18 at each end and attaches to the two fittings 12 and 14, as shown in detail in FIGS. 3-6. The proximal fitting 12 is formed by a polygonal rod segment 26 having an axial aperture 32 formed therein. The rod segment 26 is preferably metal. The number of sides of the polygonal rod segment 26 equal the number of spines 25. The flat surface of each spine 25 is positioned flat against the side of the polygonal rod segment 26 in the same orientation as the spines 25 are located in forming the basket.

15      An outer clamping ring 27, e.g., of metal, holds the spines 25 in place against the sides of the polygonal rod segment 26. An adhesive, such as polyurethane or epoxy, is preferably used to permanently fix the spines, polygonal rod segment 26, and clamping ring.

20      The proximal fitting 12 is fixedly mounted within the distal end of the inner catheter shaft 7, e.g., by epoxy, polyurethane or other adhesives. The distal end of the nylon sleeve 15 extends up to and butts against the proximal end of the polygonal rod segment 26 and clamping ring 27. The electrode lead wires 20 from each arm 9 pass through the axial aperture 32 in the polygonal rod segment 26 and then through the nylon sleeve 15.

25      Distal fitting 14 is generally the same as proximal fitting 12, in that it has a polygonal rod segment 29. The spines 25 are fixed to each side, respectively, of the polygonal rod segment 29 and are secured thereto by an outer clamping ring 30. However, no aperture is needed in segment 29 because no lead wires are present at the distal fitting. In addition, it is preferable to provide an outer plastic tip member 31, which is rounded in shape at its distal end, to help the inner catheter slide through arteries or veins with minimum trauma and to prevent trauma in the heart chamber. The tip member 31 may be fixed by using adhesive, e.g., epoxy or polyurethane.

30      The distal fitting 14 is the same size as or, if desired, may be of a smaller scale than proximal fitting 12. These fittings 12 and 14 hold the spines 25 in proper angular orientation with respect to each other, and thus maintain the

1       proper spacing of the arms 9 and the proper orientation of the basket. This is  
important because the cardiovascular catheter is subjected to a pumping heart  
wall and must also be rotated during the electrophysiological mapping process.  
In addition, the spines 25 are subjected to bending and other forces during  
5       retraction into the outer catheter and extension therefrom.

10      The basket is shown with five arms 9, which is the most preferable  
number. As shown in FIG. 7, there are at least ten useful asymmetrical positions  
of rotation. That is, the arms are placed at a first position in the heart chamber  
where readings are taken, and then the basket is rotated 36° where readings are  
again taken. As will be understood by those skilled in the art, there are an  
infinite number of orientations but only a limited amount of obtainable data is  
useful. By the use of five arms, the basket very nearly appears round in rotation  
when viewed from the end. This feature greatly facilitates placement and control  
15      within a heart chamber because the heart chambers are not round, but are  
irregular.

20      A greater number of arms is not preferred because differentiation of  
electrodes becomes more difficult and the inner catheter is more difficult to fit  
within the outer catheter. A lesser number of arms is more practical in that it is  
smaller and easier to differentiate the electrodes, but is not preferred because  
mapping becomes more cumbersome.

25      In use, the inner catheter 6 is disposed within the outer catheter 8 for  
placement in a vein or artery and then subsequently into a chamber of the heart.  
The outer catheter 8 holds the arms 9 of the basket internally in a collapsed  
position so that the entire catheter, consisting of the inner catheter 6 and the  
outer or guiding catheter 8, can be passed down the vein or artery into the heart  
chamber. Once the distal ends of the catheters have reached the desired heart  
30      chamber in the appropriate position, the outer catheter 8 is withdrawn so that  
the arms 9 flex into their predetermined "basket" position. The electrodes 11  
contact the walls of the heart chamber in this position. Additional outward  
movement of the arms and pressure against the heart wall can be gained by  
35      pushing forward on the inner catheter shaft 7 causing the basket to widen  
outwardly. When mapping has been completed, the outer catheter can be  
extended back over the basket to collapse the arms, and then ultimately be  
withdrawn with the arms therein.

35      The inner mapping or basket catheter, as described above, has several  
advantages. For example, fixing the spines of the basket at both their distal and

1 proximal ends provides a very laterally stable basket. This stability is important  
to hold the catheter in stable position within a beating heart chamber.

5 The fittings which hold the distal and proximal ends of the spines together  
the flat sides of the spines mating with the flat sides of the polygon, ensure  
accurate arrangement of the arms in three dimensions.

The semicircular cross-section of the spines increases the lateral stiffness  
in comparison with a round cross-section of equal area, thereby increasing the  
lateral stability of the basket.

10 The use of superelastic material, such as NITINOL, for the spine 25 results  
in a basket that can be bent, collapsed, and twisted without appreciable  
permanent deformation. It is thus highly resilient.

The use of five basket arms in conjunction with a high-torque catheter  
shaft achieves a basket which can readily be controlled and oriented within the  
heart chamber.

15 The use of the semicircular cross-section for the spine further allows the  
spines to fill the outwardly facing portion of the arm tubing, thus leaving the  
inwardly facing portion for the lead wires. Lead wires can thus extend through  
the tubing, and after being wrapped around the tubing can terminate at locations  
20 along the inwardly facing side of the arms away from the heart wall. Each exit  
hole and terminus can be covered and secured by adhesive. Only the outwardly  
facing portions of the lead wire which is wrapped around the tubing need be  
scraped bare to form the electrode.

25 The electrodes can thus be made quite small and are readily distinguished  
fluoroscopically from the platinum ring markers. The ring markers readily identify  
each arm of the basket, as they are arranged in a staggered or spiral form on the  
different arms.

30 The basket which is formed as described is not only laterally stiff, but is  
also quite resilient and can form itself readily to the contour of the heart  
chamber, by pushing the inner catheter forward after the basket has been  
exposed to the heart chamber through the withdrawal of the outer catheter. This  
helps ensure that all electrodes make good contact with the endocardial surface  
and provide strong electrical recording signals.

35 Referring to FIG. 9, a further embodiment is shown wherein a puller wire,  
generally designated 40, extends through the catheter 42 and is fixed to the  
distal fitting 44 of the basket, generally designated 46. The puller wire extends  
out of the proximal end 48 of the catheter and is attached to a means for  
applying a proximally directed force to the puller wire. The preferred means for

1 applying the proximal force is a deflectable control handle 50 of the type disclosed in U.S. Patent Nos. 4,960,134 and Re. 34,502 both to Webster, Jr., which are incorporated herein by reference. When the deflectable control handle is activated, the puller wire and the distal fitting to which the puller wire is connected are pulled proximally relative to the catheter thereby expanding the basket outwardly to the position shown in FIG. 10. The outward expansion of the basket forces the arms 52 against the chamber walls thereby impeding the motion of the arms relative to each other and resisting the shifting of the basket within the heart chamber.

10 The external portion 54 of the puller wire is covered with a polyurethane tube 56 which is sealed at the distal fitting 44 and the proximal fitting 58 of the basket. The polyurethane tube has a diameter between .02 and .03 inch and has flares 74 and 84 (see FIGS. 11a and 12) formed on each end by stretching the tube to form a reduced diameter portion in the center of the polyurethane tube.

15 When the polyurethane is stretched the central stretched portion becomes elastic. Because the tube is sealed at both the distal and proximal fittings, the proximal portion of the tube tends to scrunch together into an accordion-like shape 60 which in no way inhibits or interferes with the normal functions of the catheter. The polyurethane tube which is easily cleaned and sterilized prevents blood from infiltrating the puller wire and from flowing by capillary action to the internal portion of the puller wire which is infeasible to clean and sterilize. Thus, the polyurethane tube allows the catheter to be cleaned and sterilized for reuse. The internal portion 62 (see FIGS. 11a and 11b) of the puller wire is coated with TEFLON® and covered with a TEFLON® sheath 64. The TEFLON coating acts as 20 a lubricant inside of the TEFLON sheath, and the TEFLON sheath acts as a shield for the lead wires and prevents the puller wire from being impinged or pinched when the catheter is bent. Thus, the TEFLON sheath covers the puller wire preventing the puller wire from creating a large frictional force by contacting the lead wires and catheter wall. Therefore, the smooth TEFLON coated puller wire, 25 with its low coefficient of friction, easily and smoothly slides within the TEFLON sheath relative to the lead wires and catheter walls, thereby reducing the amount of force necessary to expand the basket and allowing the puller wire to translate easily in the distal direction so that the basket is easily retracted into the outer catheter 66.

30 As previously stated, the puller wire is attached to the distal fitting and the polyurethane tube is sealably attached to the distal end of the sheath. The details of these connections are illustrated in FIGS. 11a, 11b and 12.

1 Referring to FIG. 11a, the TEFLON sheath is sealably attached to the proximal flare 74 of the polyurethane tube 56. The polygonal rod segment 68 has an aperture 70 through which the lead wires 72 extend. The lead wires then extend into the arms 52. The portions of the arms and lead wires within the  
5 aperture and the clamping ring have been removed from FIG. 11a for clarity. The puller wire 40 and TEFLON sheath extend through the aperture 70 and out of the catheter. The polyurethane tube extends up to the proximal fitting and has a flair 74 at its proximal end. The TEFLON sheath extends into the flair of the polyurethane tube. The TEFLON sheath and the polyurethane tube form a circumferential lap joint which is welded 75 shut with polyurethane. The proximal fitting in the distal end of the catheter is sealed with a polyurethane seal 77 thereby preventing blood from entering the catheter. Thus, the catheter can be cleaned sterilized and reused. Further, the seal 77 prevents air from entering the heart, and thus, preventing potentially fatal air embolism. With the puller  
10 wire enclosed in the polyurethane tube, which is fixed to the distal end of the catheter, it is possible to seal the catheter without interfering with the function of the puller wire. That is, the puller wire can slide freely in a tube which is sealably fixed to the distal end of the catheter. Further the welded polyurethane seal 77 is not subject to failure because there is no packing through which the  
15 puller wire must pass.

FIG. 11b shows an alternate embodiment of the coated puller wire in which the TEFLON sheath extends all the way to the distal fitting of the basket and is sealably attached to the distal fitting. The polyurethane tube is preferred to the TEFLON sheath because the polyurethane tube is elastic, and hence, less of an accordion shape 60 is encountered with the use of the polyurethane tube.  
20

Referring to FIG. 12, the distal polygonal rod segment 76 has a bore 78 into the proximal side of the fitting. The distal end of the puller wire is inserted through a crimping tube 80 which is a hollow twenty-seven (27) gauge needle. The distal end 82 of the crimping tube is then crimped onto the puller wire, and the distal end of the crimping tube is inserted into the bore of the distal polygonal rod segment and nonremovably soldered 85 therein. The polyurethane tube also has a flair 84 at its distal end which is fitted over the proximal end 86 of the crimping tube forming a lap joint between the crimping tube and the polyurethane tube. The polyurethane tube is then welded 83 to the crimping tube with polyurethane. The distal fitting is, therefore, sealed because the soldering of the  
25 crimping tube to the polygonal rod segment seals the distal end of the puller wire.  
30  
35

1 from the blood stream and the polyurethane tube is circumferentially welded to  
the crimping tube preventing blood from reaching the puller wire.

2 The bore is centrally located in the distal rod segment, and the aperture  
3 70 through which the puller wire passes is so small relative to the basket that  
4 the puller wire is positioned substantially central with respect to the basket.  
5 Thus, the puller wire is coaxial with the central axis of the basket, and the  
outward expansion of the basket is, therefore, uniform.

6 In use, right heart catheterization is performed by inserting an introducer  
7 into the femoral vein. The introducer is then guided through the inferior vena  
8 cava, and into the right atrium, and if required, it is guided into the right  
9 ventricle. The basket catheter is then pushed through the introducer into the  
heart. Left heart catheterization is performed by inserting an introducer into the  
femoral artery. The introducer is then guided through the iliac artery, the aorta,  
10 through the aortic valve and into the left ventricle. In the alternative, a right  
11 sided approach can be used entering the left atrium transeptally. The basket  
12 catheter is then pushed through the introducer into the heart. The  
catheterization procedure can be performed with less difficulty and with less  
13 trauma to the blood vessels by the use of steerable catheters/introducers, and  
14 catheters/introducers with soft deformable tips. U.S. Patent No. 4,531,943 to  
15 Van Tassel et al., which is incorporated herein by reference, discloses a catheter  
16 with a soft deformable tip for reducing the trauma to the blood vessels during  
catheterization. U.S. Patent No. 5,045,072 to Castillo et al., which is  
incorporated herein by reference, discloses a flexible tip catheter. Further the  
17 catheters/introducers may have a predisposed bend or bends which, depending  
18 upon the type of catheterization to be performed, are bent in a certain direction  
19 to simplify that specific type of catheterization.

20 In FIGS. 13 through 16 alternate electrode configurations are illustrated  
which can be used for different types of ablation and mapping. After the  
required mapping has been performed and problematic areas are located, radio  
frequency can be provided to the electrodes of the existing catheter for ablation  
21 or if a specialized type of ablation is needed, the catheter may be removed and  
a catheter having an electrode arrangement such as that in FIG. 13 can be  
inserted into the introducer, properly oriented in the heart, and used to ablate the  
problematic tissue.

22 The electrode configuration of FIG. 13 provides a wide electrode array  
with a spiral pattern. The arms 88 have closely spaced electrodes 90 so that  
detailed mapping is obtained. The electrodes spiral down the arms 88 starting

1       with arm 88A having electrodes in the most distal position then to arm 88B with  
the electrodes being slightly proximal of the electrodes on arm 88A. The  
electrodes on arm 88C are then slightly proximal of the electrodes on arm 88B,  
and the electrodes on arm 88D are just proximal of the electrodes on arm 88C.  
5       Finally, the electrodes on arm 88E are located just proximal of the electrodes on  
arm 88D, and thus, the arm 88E electrodes are the most proximal electrodes.  
10      An angle  $\alpha$  is defined by a line 87 which is perpendicular to the axis of the  
catheter and a line 89 which is defined by the two most proximal electrodes on  
any two adjacent arms, except the A and E arms, and the angle  $\alpha$  of the spiral  
15      can be adjusted to meet the specific mapping requirements. Thus, the electrodes  
can form a circle or a spiral which spans the entire length of the basket. This  
type of electrode configuration is especially useful for mapping atrial rhythms.

FIG. 14 illustrates an electrode configuration in which three rings 92A,  
92B, and 92C of bipolar electrodes are placed around the arms 94 of the basket.  
15      This electrode configuration is especially useful for mapping and ablation in the  
right atrium. With the tip inserted into the coronary sinus opening, the most  
distal ring of electrodes 92C is positioned around the coronary sinus opening,  
and because the tip is inserted into the coronary sinus opening, the proximal ring  
20      of electrodes is located next to the edge of the coronary sinus opening. Thus,  
the right atrium can be accurately mapped around the coronary sinus opening,  
and if necessary, an ablation line can be made around the entire circumference  
of the coronary sinus opening. This method can be used with other openings in  
25      the walls of the heart chambers by adjusting the location of the distal ring 92C  
of electrodes. For openings having larger diameters, the distal ring would be  
moved proximally. Thus, the distal ring would have, when the basket is  
expanded, a diameter which is slightly greater than the diameter of the target  
opening. For openings having smaller diameters, the distal ring would be moved  
30      distally thereby reducing the diameter of the electrode ring when the basket is  
expanded.

30      FIG. 15 shows another alternate configuration of electrodes. A bipolar  
electrode 98 is placed on each arm 100. The electrodes form a narrow ablation  
line which spirals starting with the most distal electrode on arm 100A running  
to the next most proximal electrode on arm 100B to the middle electrode on arm  
100C to the next most proximal electrode on arm 100D and finally to the most  
35      proximal electrode on arm 100E. Therefore, a thin ablation line is made which  
spirals from the distal electrode on arm 100A to the proximal electrode on arm  
100E. An angle  $\beta$  is defined by a line 101 which is perpendicular to the axis of

1       the catheter and a line 103 which is defined by the two most proximal electrodes  
on any two adjacent arms except the A and E arms, and the angle  $\beta$  of the spiral  
can be varied to meet specific ablation needs. Therefore, the electrodes can  
form a circle or a spiral which spans the entire length of the basket. The  
5       electrodes used in the embodiments of FIGS. 13-15 can be rings of any suitable  
electrically conductive material, but the rings are preferably fabricated from  
platinum or alloys of platinum and iridium.

FIG. 16 shows an alternate electrode configuration in which each arm 102  
is an electrode over its entire length. Thus, the arm is a continuous electrode.  
10      Each arm comprises a NITINOL band or other inert conductive material having a  
generally semicircular cross section as shown in FIG. 17. The side 104 of the  
NITINOL band facing inwardly, that is, away from the wall of the heart chamber,  
is coated with a polyurethane coating 106 or other insulating material and thus,  
is a non-ablating area. The polyurethane, which has high viscosity and a short  
15      pot life, can be obtained from E.V. Roberts, Culver City, California by referencing  
the identification number RF-1737.

As shown in FIG. 17, the coating may also be applied to the edges 110  
of the NITINOL band. Thus, the side 108 of the NITINOL wire facing the wall of  
the heart chamber is an exposed ablation area and can transmit radio frequency  
20      energy to the heart wall for ablation. This forms a long narrow ablation line  
along the length of the electrode. Depending on where the ablation is necessary,  
a different electrode arm is chosen for the ablation. Though the electrodes  
shown are semicircular in cross-section, other cross-sectional shapes such as  
25      circular or elliptical can be utilized. These cross-sectional shapes would have  
inner and outer faces corresponding to the inner and outer sides of the band.

The inward side 104 and the edges 110 are coated to prevent the radio  
frequency energy from creating a build up of blood on the band and to reduce the  
amount of radio frequency energy necessary to perform the required ablation.  
The maximum radio frequency energy which can be transmitted by the lead wires  
30      is limited by the heating of the lead wires. By reducing the radio frequency  
energy transmitted to the blood, longer ablation lines can be made because more  
of the maximum radio frequency energy which can be transmitted by the lead  
wires is used for ablation.

Further, greater or smaller portions of the electrodes can be coated. In  
35      an alternate embodiment shown in FIGS. 18a and 18b, the entire proximal half,  
generally designated 111, or part of the proximal end of each electrode arm is  
coated with a polyurethane coating 114. The distal half, generally designated

1        116, has coating 118 on the inner side 120 and edges 122 leaving only the outer  
sides 112 of the distal half of the electrode arms uninsulated and available for  
ablation. Alternatively, as illustrated in FIGS. 19a, 19b and 19c, the entire distal  
5        half, generally designated 124, or part of the distal end of each electrode arm is  
coated with a polyurethane coating 126. The proximal half, generally designated  
128, has coating 130 on the inner side 132 and edges 134 leaving only the outer  
sides 136 of the proximal half of the electrode arms uninsulated and available for  
ablation. Thus, it can be seen that any part of the electrodes can be coated  
10      depending on the requirements of specific ablation applications. These  
embodiments serve to localize the application of the radio frequency energy to  
the area needed thereby further reducing the amount of radio frequency energy  
transmitted to the blood and tissue which does not need to be ablated. Thus,  
the total amount of radio frequency energy needed for ablation is reduced.

As shown in FIG. 5, the electrode arms can be fixed to the proximal fitting  
15      26 of the basket. The arms are then connected to the radio frequency generator  
with lead wires. This arrangement is preferred if a puller wire is used. However,  
referring to FIG. 19c, the electrode arms 146 can extend through the catheter  
142 and connect directly to the radio frequency generator. The electrode arms  
inside the catheter 142 of this embodiment have an insulating sheath 148 similar  
20      to the sheath on the lead wires, and puller wire 144 extends through the  
catheter 142.

To apply the polyurethane coating to the NITINOL band, the polyurethane  
is dissolved in a solvent composed of approximately two parts tetrahydrofuran  
25      to one part p-dioxane which lowers the viscosity of the polyurethane for  
application to the electrode arm. Tetrahydrofuran can be obtained from Aldrich  
Chemical Co., Inc., Milwaukee, Wisconsin, and p-dioxane can be obtained from  
E.M. Science, Gibbstown, New Jersey. Once the polyurethane is completely  
dissolved in the solution, the solution is applied to the arms of the electrode to  
cover the non-ablating areas of the electrode arms discussed above. The  
30      solution can be applied by painting it onto the electrode with an artist's brush,  
dipping the electrode, submerging the electrode, or spraying the solution onto the  
electrode. Alternatively, the coating can be obtained by dipping the electrode in  
a latex solution and completely coating it with a very thin coating of an  
elastomer such as a polyurethane latex with a shore hardness of 50 D or less.  
35      The latex is then fully cured by heating in a dry oven. When the electrode arm  
is coated by submerging or dipping, the coating is removed from the ablating  
areas of the electrode by sandblasting with a Comco sandblaster using sodium

1 bicarbonate which is directed in a well defined jet at the ablating areas of the electrodes. The jet of sodium bicarbonate removes the coating with high resolution leaving the electrode undamaged.

5 To assure the accurate application of the solution, the portions of the electrodes which are not to be coated can be covered with a tape 138 (see FIG. 19a) thereby preventing solution from directly contacting the electrodes in those areas. The tape 138 is adhesive on one side so that it can be added to the outer surface 136 of the electrodes, and it is fabricated from a material capable of withstanding the curing temperatures of the solution. The masking process  
10 simplifies the coating of electrodes having different cross-sections such as circular and provides a method for controlling the width of the ablation line. The electrode with the solutions thereon are then heated for approximately 2 hours at approximately 100°C or until the polyurethane has cured. Though polyurethane is preferred, other electrically insulating materials which are bio-  
15 compatible and maintain adhesion in the vascular system can be used. The tape is then removed after curing.

20 The invention has been described in its preferred embodiment. Numerous variations of the invention will be evident to those of ordinary skill in the art. The appended claims not only cover the preferred embodiment, but also such variations.

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1       **WHAT IS CLAIMED IS:**

1.       A catheter for cardiac mapping and ablation comprising:  
a catheter body having a distal end and a lumen;  
5           a plurality of arms extending through the lumen and out the distal  
end of the catheter forming a three-dimensional shape; and  
the arms comprising a continuous electrode.
- 10       2.       The catheter of claim 1 wherein the arms have distal end and  
further comprising a distal fitting fixing the distal ends of the arms thereto.
- 15       3.       The catheter of claim 1 wherein the arms have a portion inside the  
catheter body which is insulated.
- 20       4.       A mapping and ablation catheter comprising:  
a catheter body having a lumen and a distal end; and  
a plurality of continuous electrode arms extending from the distal  
end of the catheter forming a three-dimensional shape.
- 25       5.       A catheter basket electrode configuration for use with a catheter,  
the electrode configuration comprising a plurality of continuous electrode arms  
each arm having a proximal end and a distal end and the arms forming a  
three-dimensional shape.
- 30       6.       The configuration of claim 5 wherein the proximal ends of the arms  
are fixed together and the distal ends of the arms are fixed together and the arms  
are expanded radially outward forming the three-dimensional shape.
- 35       7.       The configuration of claim 5 wherein at least one arm is partially  
insulated.
8.       The configuration of claim 5 wherein each arm is partially  
insulated.

1           9. A method for coating a continuous electrode with an insulating coating comprising the steps of:  
               dissolving an insulator in a solvent to form a solution;  
               applying the solution to non-ablating areas of the continuous  
5           electrode; and  
               curing the solution with heat.

10           10. The method of claim 9 wherein the solvent is approximately one part p-dioxane and two parts tetrahydrofuran.

10           11. The method of claim 9 wherein the insulator is polyurethane.

15           12. The method of claim 9 wherein the solution is applied with an artist's brush.

15           13. The method of claim 9 wherein the solution is applied by dipping the electrode in the solution and further comprising the step of removing the cured coating from ablation areas of the electrode.

20           14. The method of claim 13 wherein the cured coating is removed with a high pressure solution propelled at the coating.

25           15. The method of claim 9 wherein the solution is applied by spraying the solution onto the electrode.

25           16. The method of claim 9 wherein the solution is applied to an inner surface of the electrode.

30           17. The method of claim 9 wherein the solution is applied to an inner surface of the electrode and to a proximal end of the electrode.

30           18. The method of claim 9 wherein the solution is applied to an inner surface of the electrode and to a proximal half of the electrode.

35           19. The method of claim 9 wherein the solution is applied to an inner surface of the electrode and to a distal end of the electrode.

1           20. The method of claim 9 wherein the solution is applied to an inner  
surface of the electrode and to a distal half of the electrode.

5           21. A method for coating a continuous electrode comprising:  
dipping the electrode in latex to form an insulating coating of the  
electrode;  
curing latex with heat; and  
removing the coating from the ablation areas of the electrodes.

10          22. The method of claim 21 wherein the coating is removed with a  
high pressure solution propelled at the coating.

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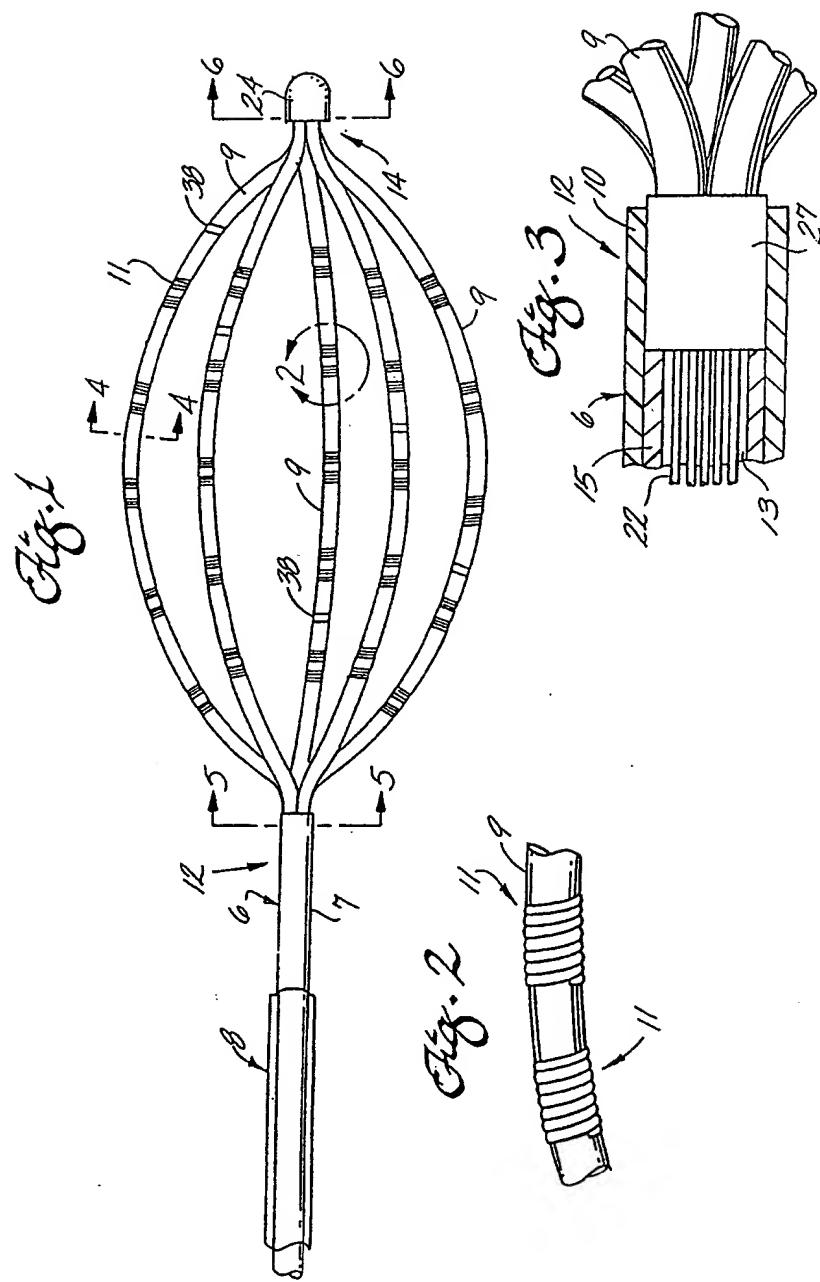
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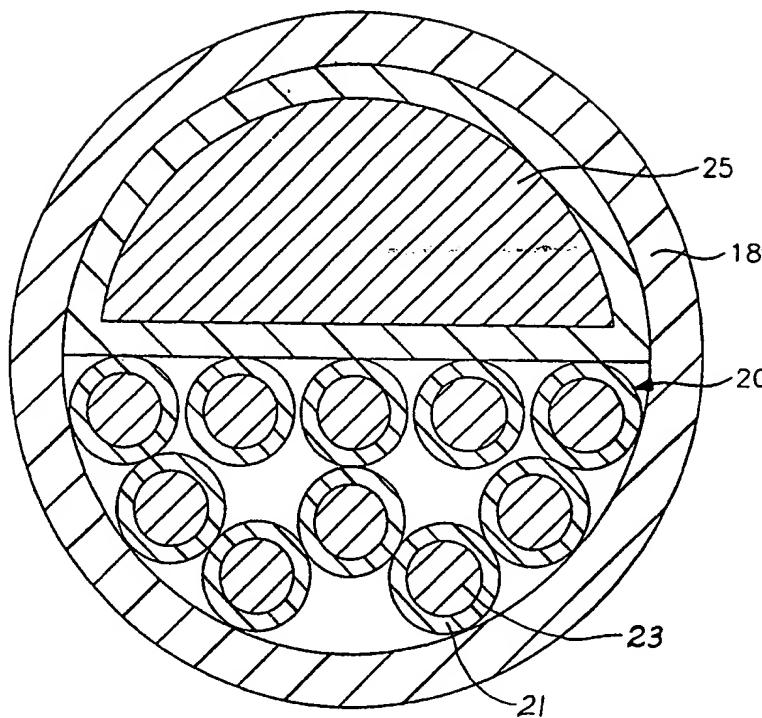
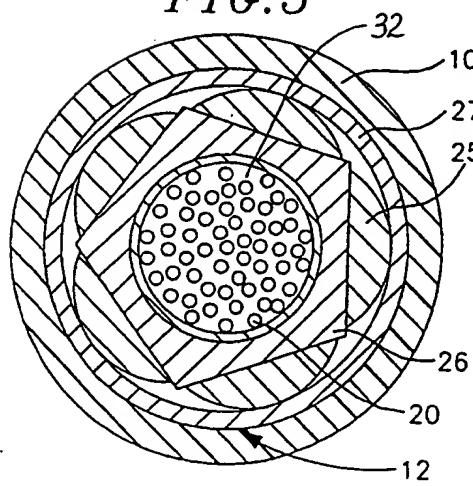
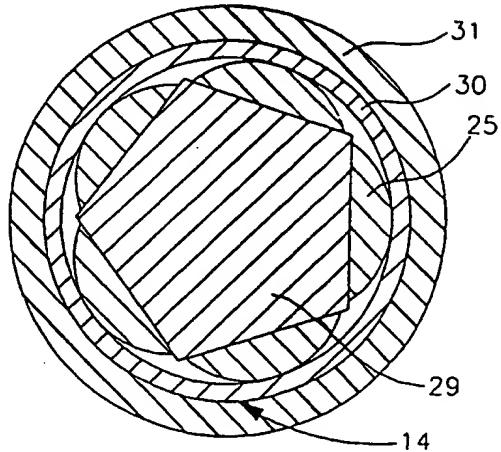
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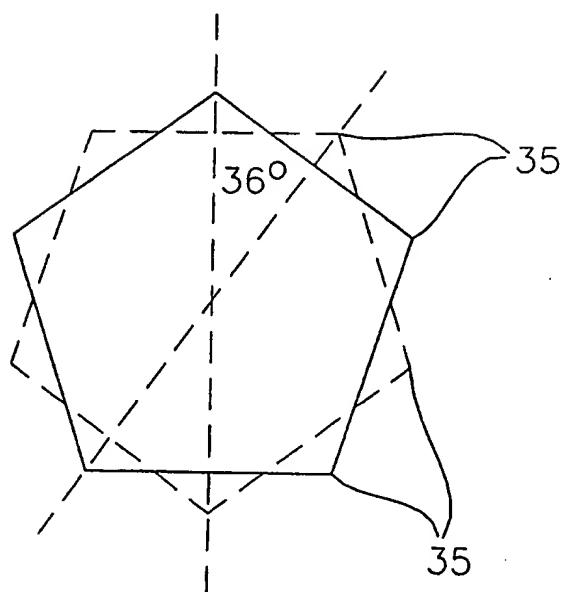


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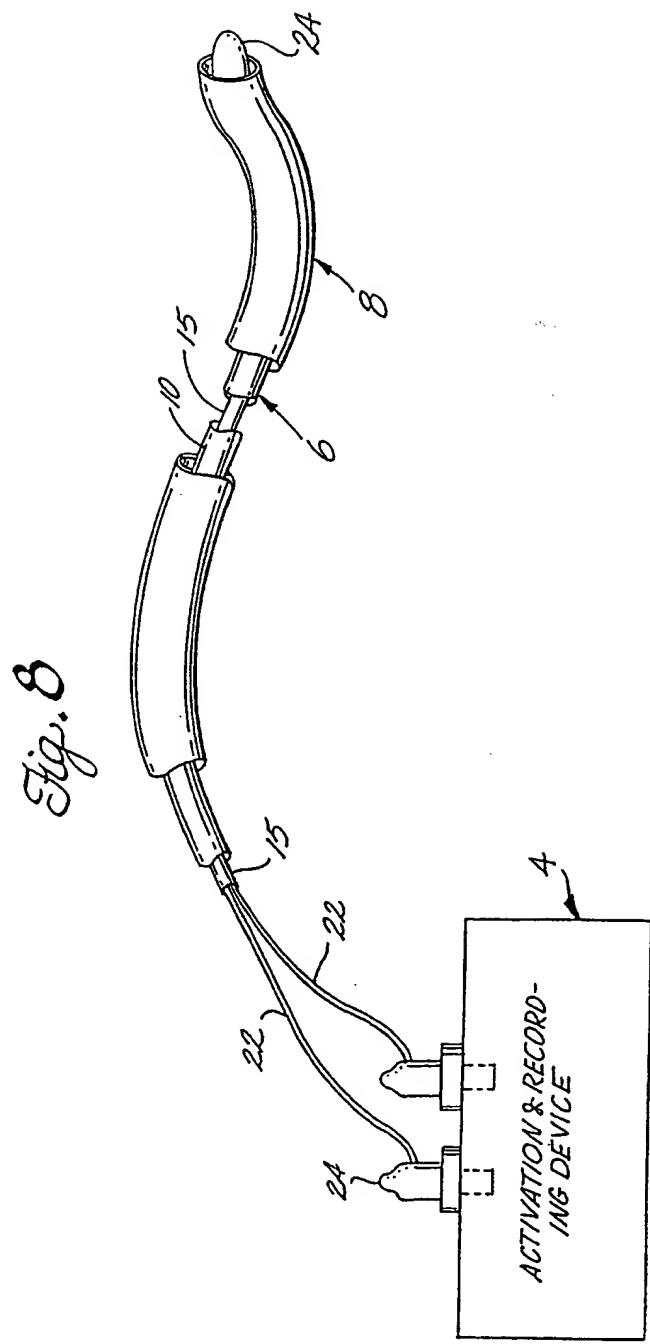
*FIG. 4**FIG. 5**FIG. 6*

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FIG. 7



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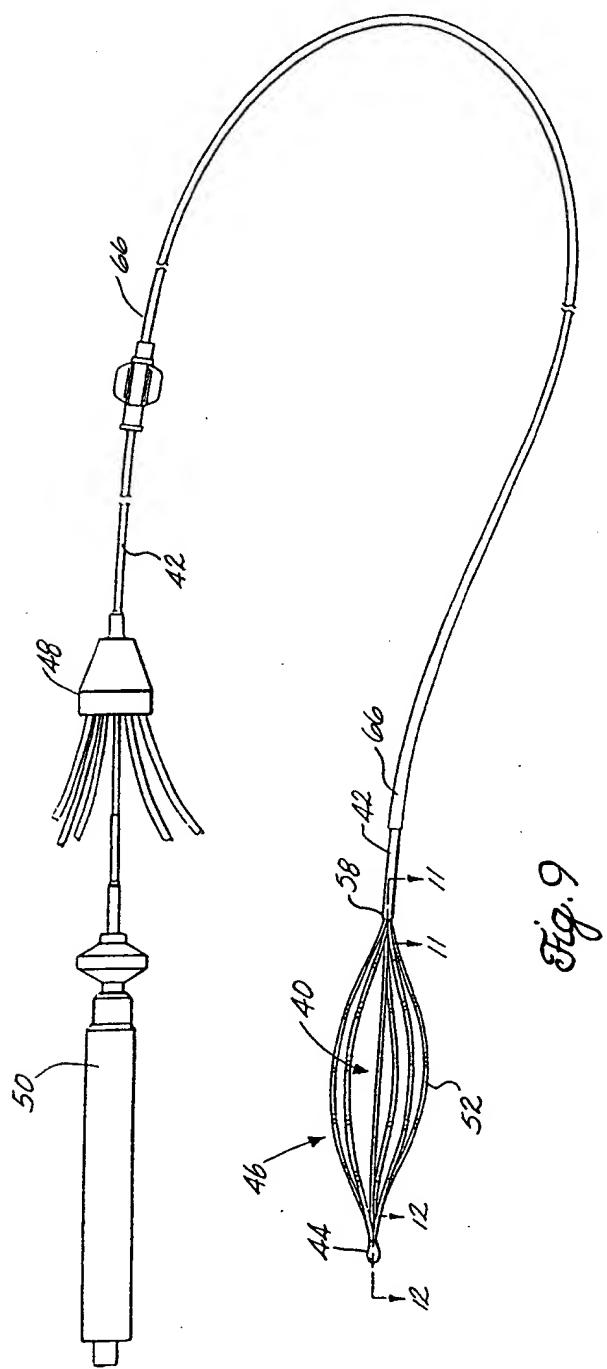


Fig. 9

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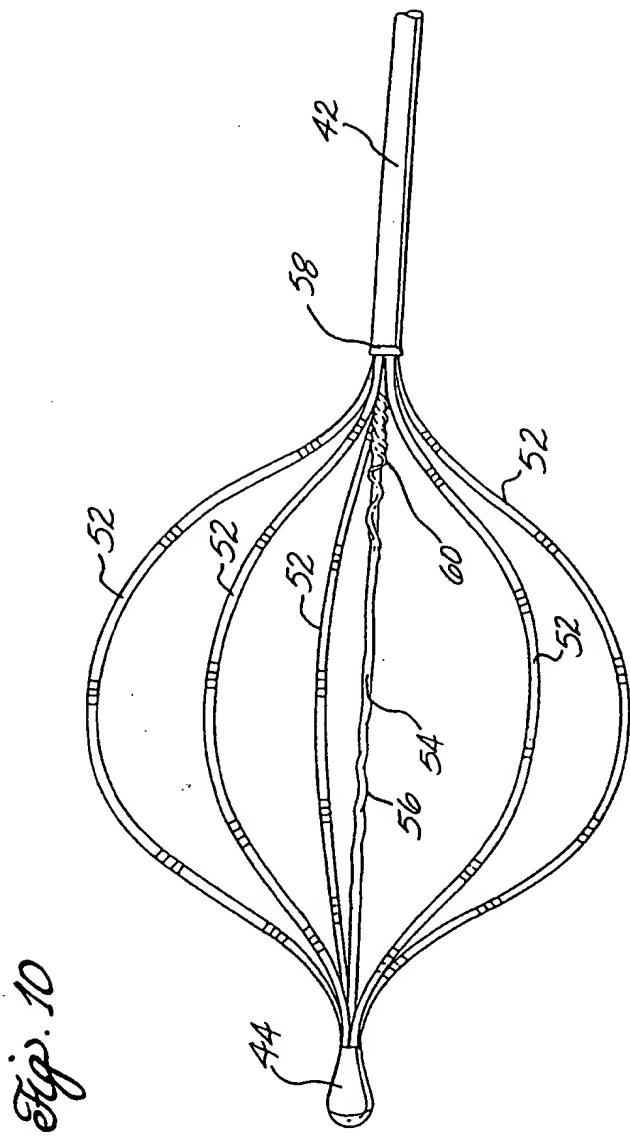
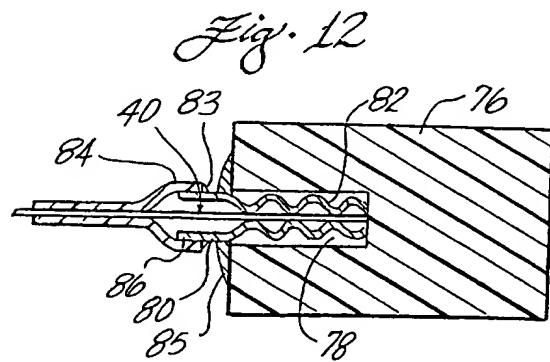
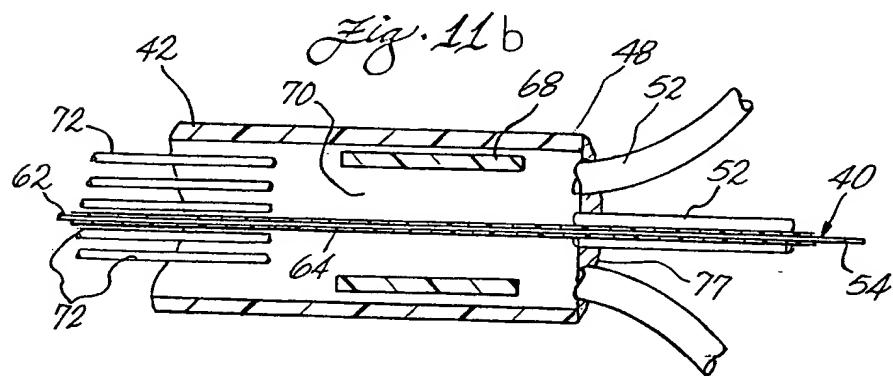
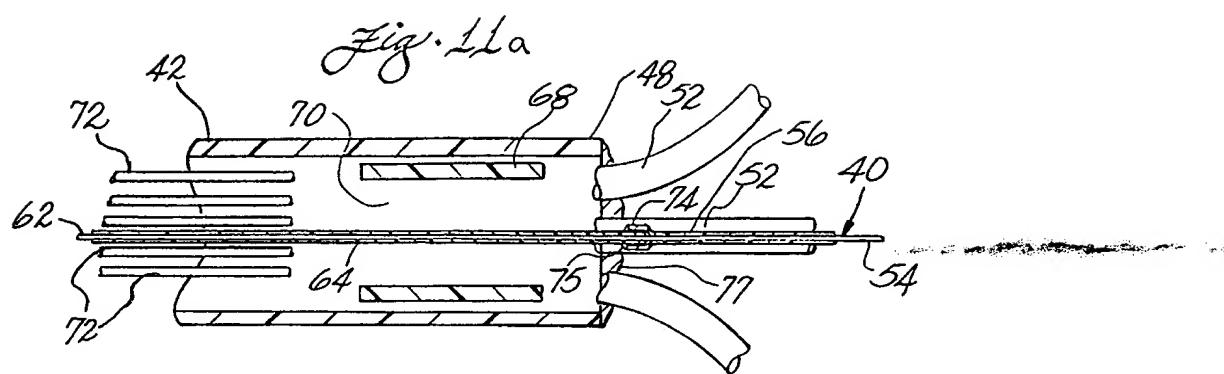


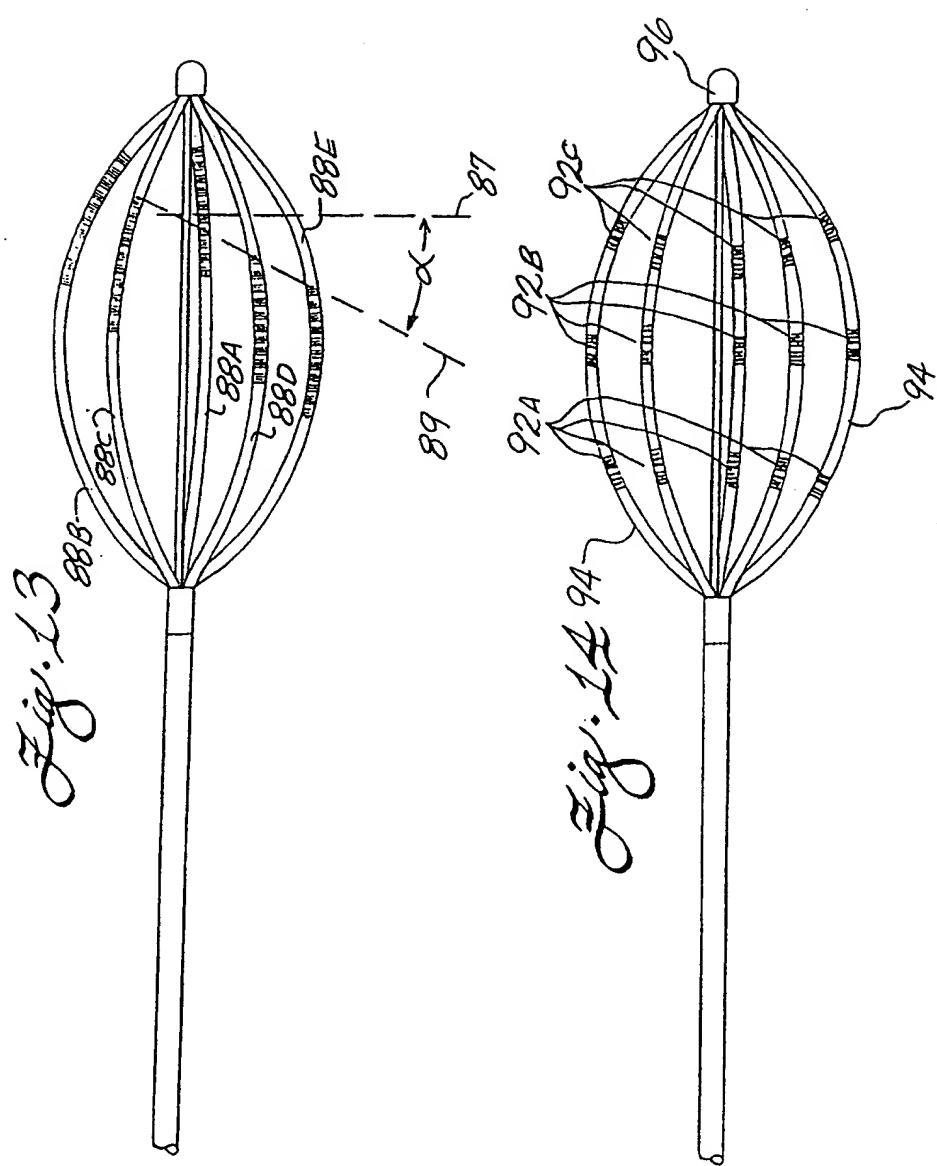
Fig. 10

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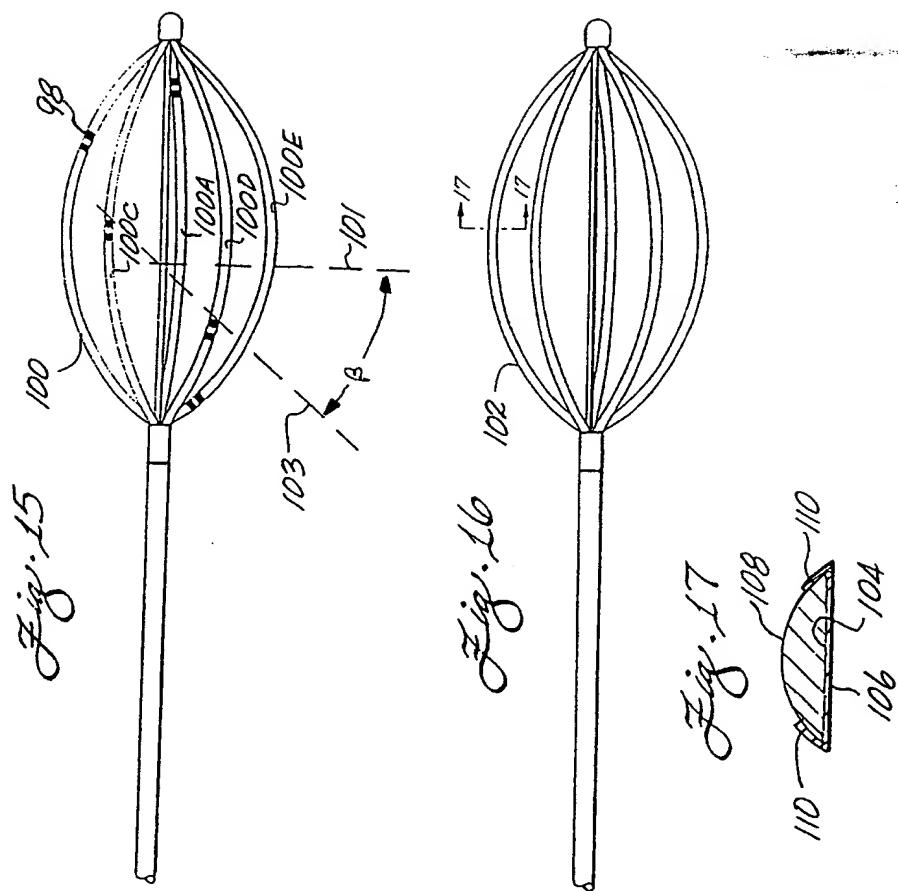
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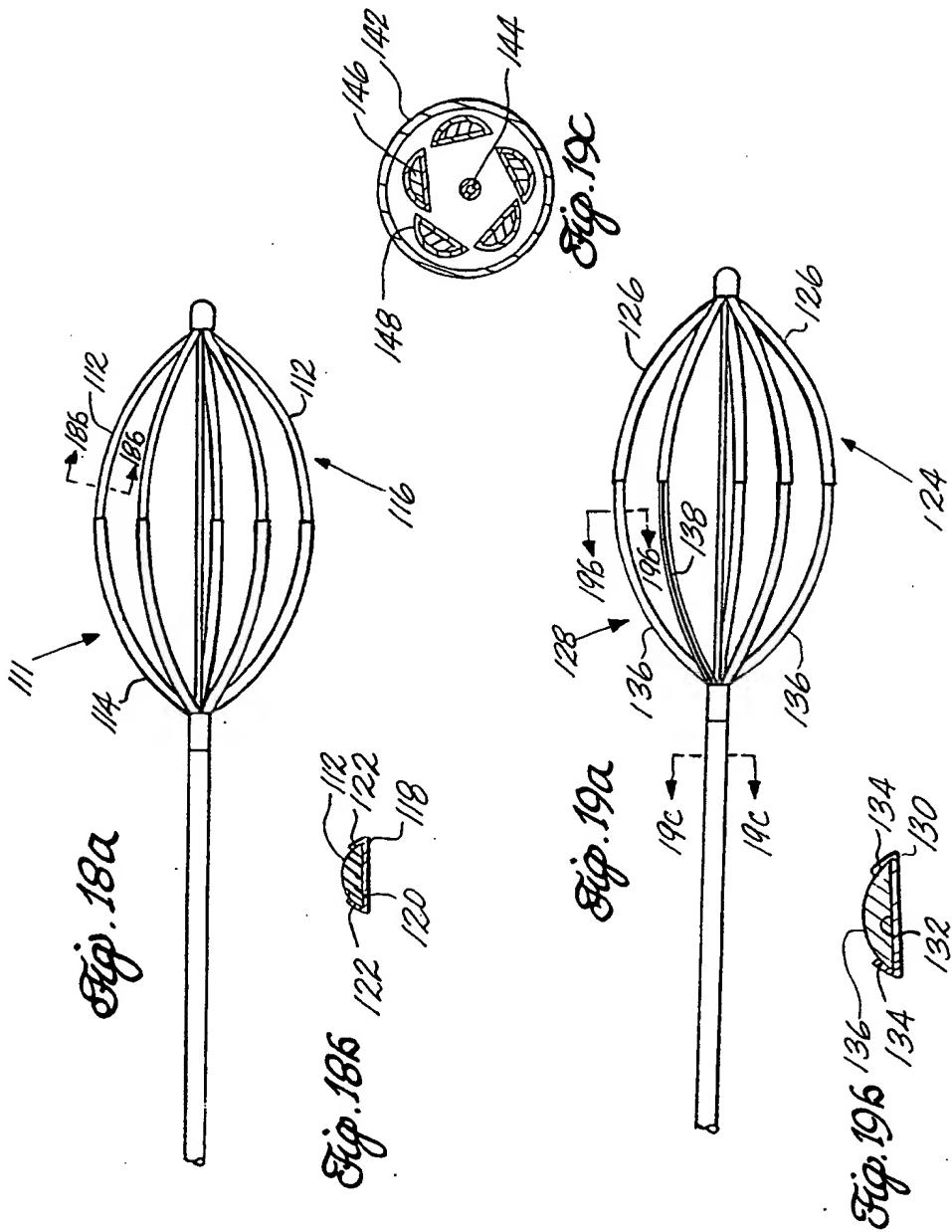
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9/10



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## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US96/06133

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(6) :A61B 5/0402; A61N 1/05  
 US CL :29/885; 128/642; 606/41; 607/122, 126

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 29/885; 128/642; 606/41; 607/122, 126

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US, A, 5,311,866 (KAGAN ET AL.) 17 May 1994, see column 2 line 43 to column 5 line 10.	1-8 -----
---		9-22
A		
A	US, A, 5,449,381 (IMRAN) 12 September 1995, see entire document.	1-22
X	FR, A, 2659 240 (GALLEY) 13 September 1991, see Abstract.	1-8 -----
---		9-22
A		
X	WO, A, 89/06148 (EDHAG) 13 July 1989, see page 5 line 23 to page 9 line 23.	1-6

Further documents are listed in the continuation of Box C.

See patent family annex.

• Special categories of cited documents:	T	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
*A* document defining the general state of the art which is not considered to be part of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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Date of the actual completion of the international search

21 JULY 1996

Date of mailing of the international search report

08 AUG 1996

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